IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	**Master File No. 2:12-MD-02327** **MDL 2327**
THIS DOCUMENT RELATES TO: *Ethicon Wave 8 cases listed in Exhibit A*	**JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

PLAINTIFFS' MEMORANDUM IN SUPPORT OF THEIR MOTION TO EXCLUDE THE GENERAL CAUSATION OPINIONS OF DEFENSE EXPERT AHMET BEDESTANI, M.D.

Dr. Ahmet Bedestani did not attend medical school in the United States; the school that he attended is not accredited in the United States; and by the time he passed his boards and gained employment as a physician, the device about which he hopes to opine, Ethicon's Prosima, had been pulled from the market. For these and other reasons, Dr. Bedestani is unqualified to offer opinions on the safety and efficacy of the Prosima device, and his opinions should be excluded entirely. In the alternative, several of Dr. Bedestani's opinions should be stricken, based on either his lack of qualifications or lack of a reliable methodology.

Most of Dr. Bedestani's expert report lacks opinions at all. Rather it is a general analysis of mesh, of prolapse, and of the Prosima device—which was designed to treat Pelvic Organ Prolapse ("POP") during its brief, approximately three-year run on the market. Finally, in the last paragraph, Dr. Bedestani offers the following opinions:

- Prosima was safe and effective, offering better outcomes than native tissue repair;

- The warnings in the IFU were adequate and properly accounted for a surgeon's common knowledge of the risks;
- The design defect allegations of the Plaintiffs' experts are without merit;
- The benefits of the Prosima outweighed the risks; and
- The product was "state of the art" at the time of launch, and "I do not know how it could have been made any safer." (General Expert Report of Ahmet Bedestani, M.D., attached as Exhibit B, at p. 28)

At the very least, this Court should prevent Dr. Bedestani from giving the second, third and fifth opinions, as they go beyond the scope of his expertise, and/or they are *ipse dixit* opinions that lack analysis or evidentiary support.

LEGAL STANDARD

Federal Rule of Evidence 702 sets forth the basic framework for analyzing the admissibility of expert opinions. The rule reads, in pertinent part, as follows:

> If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise, if (1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case.

Fed. R. Evid. 702. On the issue of qualifications, "the district court must decide whether the expert has 'sufficient specialized knowledge to assist the jurors in deciding the particular issues in the case.'" *Belk, Inc. v. Meyer Corp., U.S.*, 679 F.3d 146, 162 (4th Cir. 2012), *as amended* (May 9, 2012) (quoting *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 156 (1999)).

If the witness is suitably qualified, then the *Daubert* inquiry generally breaks down into a two-step analysis. The first issue is whether the proffered evidence represents "scientific

knowledge," meaning that it is supported by appropriate validation. The second issue is whether the evidence would assist the jury—i.e., whether it is relevant. *United States v. Dorsey*, 45 F.3d 809, 813 (4th Cir. 1995). The relevance aspect of the inquiry is often discussed in terms of whether the expert's opinions "fit" the case. *See Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 591-92 (1993).

To meet the standard of reliability, the testimony "must be supported by appropriate validation—i.e., 'good grounds,' based on what is known. In short, the requirement that an expert's testimony pertain to 'scientific knowledge' establishes a standard of evidentiary reliability." *Benedi v. McNeil-P.P.C., Inc.*, 66 F.3d 1378, 1383 (4th Cir. 1995).

There are five factors courts often consider, taken from the *Daubert* opinion, in assessing the reliability of expert testimony:

- (1) whether the testimony has been tested,
- (2) whether it has been published or exposed to peer review,
- (3) its rate of error,
- (4) whether there are standards and controls over its implementation, and
- (5) whether it is generally accepted.

See Cavallo v. Star Enterprise, 100 F.3d 1150, 1158 (4th Cir. 1996). However, "the factors discussed in *Daubert* were neither definitive, nor exhaustive." *Cooper v. Smith & Nephew, Inc.*, 259 F.3d 194, 199 (4th Cir. 2001).

Courts should focus on expert witnesses' "principles and methodology, not on the conclusions that they generate." *Md. Cas. Co. v. Therm-O-Disc, Inc.*, 137 F.3d 780, 783 (4th Cir. 1998). This is because "*Daubert* governs whether evidence is admitted, not how persuasive it must be to the factfinder." *Cavallo*, 100 F.3d at 1158.

ARGUMENT

For the reasons stated below, Dr. Bedestani's opinions should be excluded in their entirety. Alternatively, he should be precluded from opining about warnings, about design issues, and about whether the product was the state of the art (or could have been made safer).

I. Dr. Bedestani's opinions about the safety and efficacy of Prosima should be excluded because he is not qualified to give such opinions, and because he did not employ a reliable methodology. Dr. Bedestani never used the product as a physician, does not use mesh now, and did not consider important authorities that contradict his opinions on degradation.

Dr. Bedestani does not fit the typical profile for an expert in this MDL. He did not attend a medical school accredited in the United States, and he has never, as a physician, used mesh to repair pelvic organ prolapse. Yet, Ethicon has put him forth as an expert to explain why the Prosima mesh was a safe and effective product. Much of Dr. Bedestani's report leads to the first and fourth opinions in the bullet points above: that Prosima was safe and effective, offering better outcomes than native tissue repair; and that the benefits of the Prosima outweighed the risks. The Court should strike these opinions because Dr. Bedestani is not qualified to give them, and because they are not reliable.

Under Rule 702, an expert may be qualified by "knowledge, skill, experience, training, or education." The party that is putting forth the expert has the burden of proving that the expert is suitably qualified. *See Cooper v. Smith & Nephew, Inc.*, 259 F.3d 194, 199 (4th Cir. 2001) (stating that the proponent of expert testimony "must establish its admissibility by a preponderance of proof"). As noted above, this Court must assess "whether the expert has sufficient specialized knowledge to assist the jurors in deciding the particular issues in the case." *Belk*, 679 F.3d at 162. Reliability is determined by assessing the expert's methodology in reaching his opinions. *Md. Cas. Co.*, 137 F.3d at 783.

The Defendants have not established that Dr. Bedestani is qualified to opine about the safety or efficacy of Prosima's mesh, including whether the risks outweigh the benefits. If his own testimony is to be believed, Ethicon's proffered "expert" has the unusual distinction of being rejected from every medical school in the United States. Dr. Bedestani testified that there were 132 medical schools in the United States when he applied, and they all rejected him "not once but twice. I have a binder somewhere with it." (Bedestani Dep. Tr., attached as Exhibit C, at 78:23-74:8). Fortunately for Dr. Bedestani, "there was no MCAT policy at Dominica Ross University School of Medicine." The school was on the island of Dominica.[1] (*Id.* at 80:7-12). Dr. Bedestani had friends there, so, in his own words, he "said screw it and … went down there." (*Id.* at 79:19-80:4). He acknowledged that the school was not accredited in the United States. (*Id.* at 81:1-5). However, his degree allowed him to take medical licensing exams in the United States. (*Id.* at 80:16-23). Dr. Bedestani passed his OB and gynecology licensing exams in November 2011. (*Id.* at 24:11-15). Although Dr. Bedestani did use the Prosima as a fellow, he stopped using it before it was taken off the market in 2011, because he was not practicing medicine at that time. (*Id.* at 109:2-15). By the time his practice was up and running in 2012, Prosima was off the market. (*Id.*). Thus, Dr. Bedestani never used the Prosima device as a physician—only as a fellow before he passed his boards.

Dr. Bedestani's lack of qualification is further evidenced by the fact that he has never been asked to serve as an expert witness before. (*Id.* at 84:1-6). While that fact is not dispositive by itself—every witness has a first case, after all—it is notable in the context of this litigation. The mesh litigation, involving numerous products, has been ongoing for almost the entirely of Dr. Bedestani's seven-year career as a physician, and this Ethicon Wave 8 marks the first time that he has been called upon as a potential expert by anyone.

[1] Unfortunately, the school had to close after the island was battered by Hurricane Maria. (*Id.* at 80:7-12).

It is also noteworthy that despite his report discussing the virtues of mesh, Dr. Bedestani does not use mesh to repair POP in his own practice. He testified that a surgery called abdominal sacrocolpopexy ("ASC") has been his most common technique for treating prolapse in the last three years, but he has also used other methods of native tissue repair. (*Id.* at 60:15-61:18). Dr. Bedestani does not use any type of transvaginal mesh in his practice. (*Id.* at 62:7-14). Dr. Bedestani's non-use of mesh bears on two aspects of the *Daubert* inquiry. As to qualifications, it shows that he is not learning about the product by actually using it, so he is not becoming qualified through experience and/or knowledge.

His failure to use mesh in his practice also bears on the reliability issue. Dr. Bedestani's report opines, among other things, that the Prosima offered better benefits and outcomes to patients than native tissue repairs. (Bedestani Report at 28). Yet, with Prosima unavailable, he has not gone to the theoretical next-best option—another mesh product. He uses the supposedly inferior native tissue repairs. Thus, he has not employed "in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field." *Eghnayem v. Boston Sci. Corp.*, 57 F. Supp. 3d 658, 675 (S.D.W. Va. 2014) (citing *Cooper*, 259 F.3d at 203; and *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 152 (1999)). Unless Dr. Bedestani can offer a compelling argument as to why Prosima was substantially better than all other mesh products—which he has not done—his clinical practice and litigation position are directly at odds.

Another reliability issue for Dr. Bedestani, with regard to his opinions on the safety and efficacy of Prosima, is that he has not studied key evidence on the central issue of degradation. Much of Dr. Bedestani's report is devoted to his position that the polypropylene in the Prosima does not degrade *in vivo*. (*See, e.g.*, Bedestani Report at p. 25, noting the Plaintiffs' experts' opinion that the mesh degrades and stating that it "lacks merit and is not true"). It appears that

Dr. Bedestani has relied only on favorable evidence in reaching this conclusion, without studying the contrary evidence, as it required of litigation experts. *See, e.g., In re C. R. Bard, Inc., Pelvic Repair Sys. Prod. Liab. Litig.*, No. MDL 2187, 2018 WL 4220616, at *4 (S.D. W. Va. Sept. 5, 2018) ("The reliability of an expert's opinion comes into question when he has not acknowledged or accounted for science that refutes his position.").

Notably, Dr. Bedestani billed only 64.4 hours for all of his work on the case, despite authoring a 28-page report with well over 100 footnotes. (Bedestani Dep. at 7:5-13). During his abbreviated study period, he did not review any Ethicon internal documents addressing the safety of the Prosima. (*Id.* at 29:3-13). Such evidence certainly existed. For instance, one pre-launch e-mail discussed comments by Vince Lucente, one of Ethicon's primary consultants, who described the Prosima as a "reckless" product. (Rosalyn Harcourt e-mail to Jonathan Meek, April 23, 2008, at ETH.MESH.05009194, attached as Exhibit D).

During Dr. Bedestani's deposition, counsel asked him about a June 2011 study done for Johnson & Johnson by PA Consulting Group. This in-depth analysis addressed mesh erosion in the pelvic floor, but it also touched on related issues such as degradation. One section is titled: "Polypropylene can suffer from degradation following implant." (PA Consulting Group: *Investigating Mesh Erosion in the Pelvic Floor*, June 22, 2011, attached as Exhibit E, at p. 35). The study explains how oxidation in the body leads to degradation of the material after implant. (*Id.*). Dr. Bedestani knew nothing about the PA Consulting study. (Bedestani Dep. at 54:19-56:23). He was also unfamiliar with one of Ethicon's most notable studies, known as the "seven-year dog study." (*Id.* at 57:4-12). That study showed, at the seven-year point, that "[d]egradation in PROLENE is still increasing and PVDF, even though a few cracks were found, is still by far the most surface resistant in-house made suture in terms of cracking." (Mark

Cafone, *Seven Year Data for Ten Year PROLENE Study*, Oct. 15, 1992, attached as Exhibit F, at ETH.MESH.09888188). There is no indication that Dr. Bedestani considered this report or other evidence showing that polypropylene **does** degrade *in vivo*.

For all of these reasons, this Court should conclude that Dr. Bedestani is not qualified to offer opinions about the safety and efficacy of Prosima, and/or that he did not use a reliable methodology in reaching those opinions. Thus, the following opinions should be excluded:

- Prosima was safe and effective, offering better outcomes than native tissue repair;
- The benefits of the Prosima outweighed the risks. (*See* Bedestani Report at 28).

II. The analysis above applies equally to Dr. Bedestani's remaining opinions, but there are additional reasons to exclude his opinions that the warnings issued by Ethicon were adequate, that the Prosima was not defectively designed, and that the Prosima was a "state of the art" product.

The analysis above similarly applies to Dr. Bedestani's remaining opinions. His lack of general qualifications, and lack of a reliable methodology, should prevent him from opining about warnings, about design defects, and about whether the Prosima was a "state of the art" product. But there are additional reasons why each of those opinions should be excluded, and those reasons are addressed below.

A. Dr. Bedestani has no expertise in warnings, and this Court has held that additional experience or knowledge is required to opine about the sufficiency of warnings.

By his own admission, Dr. Bedestani is not an expert on warnings. Although his report contains several opinions about the purported sufficiency of the warnings in the Prosima Instructions for Use ("IFU"), neither Dr. Bedestani's report nor his deposition establish that he is qualified to give such opinions.

As to warnings, this Court has made clear that simply working as a urogynecologist, without more, is insufficient to be classified as an expert on warnings. *See In re C.R. Bard, Inc.*,

948 F. Supp. 2d 589, 611 (S.D.W. Va. 2013), *on reconsideration in part* (June 14, 2013) ("Despite his stellar qualifications as a urogynecologist, Dr. Shull is unqualified to testify on the specific issue of product warnings, as evidenced by his lack of familiarity with the process."). Here, no medical device company has ever asked Dr. Bedestani to help draft a product label associated with a medical device. (Bedestani Dep. at 84:7-11). No medical device company has asked Dr. Bedestani to review the adequacy of a product label associated with a medical device. (*Id.* at 84:14-18). Dr. Bedestani is unfamiliar with the industry standards that govern what warnings information is required to be in a product label. (*Id.* at 84:25-85:5). And, Dr. Bedestani acknowledged that he has "never reviewed the mandates from the [FDA] and how that governs labeling." (*Id.* at 85:8-15). When asked if he was familiar with a failure modes and effects analysis ("FMEA"), which is used to determine which warnings may be necessary, Dr. Bedestani replied: "I think I was more familiar with it from my fascination with aviation, where certain components of aircraft would be – or even automobile, to see if it – to see failure levels on even piping in one's home." (*Id.* at 85:23-86:6).

Finally, Dr. Bedestani essentially admitted his lack of expertise with regard to warnings in the following colloquy:

> Q. [I]s it safe for me to assume that you don't consider yourself an expert in the warnings information that [is] included in the product label?
>
> A. I don't think that I was ever in a position to dictate what should or should not be in a warning label. But I do believe that it's my responsibility to make other people aware if there were problems with certain applications of certain technologies, ergo in a paper, and I think did that in the complications of transvaginal mesh.

(*Id.* at 91:18-92:3). Later, when asked if he was an expert in "what warning statements need to be in a product label for a medical device," he responded that he has "never been put in a capacity to do that." (*Id.* at 94:5-9).

Clearly, Dr. Bedestani lacks the experience, training, and knowledge necessary to qualify as an expert on product warnings, so he should be precluded from testifying as to the adequacy of the Prosima IFU.

B. Dr. Bedestani has no expertise in chemistry, and he has not demonstrated any specialized knowledge regarding the design of medical devices; thus, his design defect opinions should be stricken.

The Court should also preclude Dr. Bedestani from opining about whether the Prosima was defectively designed. There is no evidence that Dr. Bedestani has any knowledge or experience related to the design of medical devices, and there is ample evidence that he does not.

As noted, Dr. Bedestani's opinion is based in part on his assertion that the polypropylene does not degrade. Yet, he acknowledged that he has no expertise in polymer chemistry, adding that he "had to take organic chemistry a couple of times. It was a hard class." (Bedestani Dep. at 86:17-20). Dr. Bedestani has never consulted with a manufacturer regarding the material that should be used in a medical device. (*Id.* at 90:23-91:3). Dr. Bedestani is not an expert in the mesh selection process, as it relates to stiffness, porosity, density, and weight. (*Id.* at 91:10-17). As noted above, he does not actually use mesh in his practice. (*Id.* at 60:15-61:18). Simply put, there is nothing in his personal history or his deposition that shows any specialized knowledge with regard to the design of this medical device, or with regard to medical devices in general.

Plaintiffs recognize that certain urogynecologists have been permitted to opine about mesh properties, as it relates to the design defect inquiry. *See, e.g.*, *Huskey v. Ethicon, Inc.*, 29 F. Supp. 3d 691, 706–07 (S.D. W. Va. 2014) (allowing Dr. Bruce Rosenzweig's testimony on properties of mesh, including degradation). However, experts such as Dr. Rosenzweig have vastly superior experience and have demonstrated a wealth of knowledge on the topic. *See id.* at 707 (noting that Dr. Rosenzweig had performed more than 1,000 pelvic floor surgeries, including

more than 200 dealing with complications related to synthetic mesh). Here, Dr. Bedestani used the Prosima approximately 40-to-100 times as a fellow, before he was certified as a physician. (Bedestani Dep. at 26:13-19). He never used the Prosima as a physician, as it was already off of the market. (*Id.* at 109:2-15). Thus, he has neither the volume nor the quality of experience that would be necessary to qualify him to opine about the design of the mesh, including related issues such as degradation. Thus, the Court should exclude the opinion that the design defect allegations of the Plaintiffs' experts are without merit. (*See* Bedestani Report at 28).

C. There is no evidentiary or analytical basis for Dr. Bedestani's claim that the Prosima was the "state of the art" when it was on the market; rather, it is an *ipse dixit* opinion that should be excluded under *Daubert*.

The Court should also preclude Dr. Bedestani from offering any opinions as to whether the Prosima device was the "state of the art." Dr. Bedestani does not offer any comparison of the Prosima with other devices to explain why Prosima was the "state of the art." (*See* Bedestani Report at 27-28). The analysis above also explains why Dr. Bedestani is not qualified to opine as to the "state of the art." As someone who never used Prosima as a physician and does not currently use mesh, he simply does not have the knowledge base to make that judgment.

It appears that Dr. Bedestani's opinion is based on his conclusion that "I do not know how [Prosima] could have been made any safer." (Bedestani Report at 28). Of course, the mere fact that Dr. Bedestani does not know how Prosima could have been made safer says nothing about whether the device actually could have been made safer. One way it could have been made safer was for it not to have been made with a material that degrades in the human body. As discussed above, there are numerous Ethicon documents discussing degradation of the polypropylene mesh, but Dr. Bedestani did not review this evidence that contradicts his opinions.

See In re Bard, 2018 WL 4220616, at *4 ("The reliability of an expert's opinion comes into question when he has not acknowledged or accounted for science that refutes his position.").

While this phrase is overused by attorneys seeking to exclude experts, Dr. Bedestani's "state of the art" opinion is truly an *ipse dixit* opinion. *See Knight v. Boehringer Ingelheim Pharm., Inc.*, 323 F. Supp. 3d 809, 821 (S.D. W. Va. 2018) (quoting *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997)) (stating that "nothing in either *Daubert* or the Federal Rules of Evidence requires a district court to admit opinion evidence that is connected to existing data only by the *ipse dixit*[—translation: "he himself said it"—]of the expert"). Dr. Bedestani asks this Court to conclude that the Prosima was "state of the art" based merely on the fact that "I do not know how it could have been made any safer." (Bedestani Report at 28). Apparently Ethicon could not figure that out, either, as the product was removed from the market. But an inability to fix an unsafe product does not make the product the "state of the art." There is no analysis in Dr. Bedestani's report as to why the Prosima was the "state of the art"—the phrase appears only twice, in conclusory fashion. (*Id.* at 27, 28). This opinion, therefore, is an unsupported *ipse dixit* opinion that should be excluded.

CONCLUSION

Dr. Bedestani did not attend medical school in the United States, where he was apparently rejected twice by every single school. He did not use the Prosima mesh device at any time while he was qualified as a physician, and he does not use any transvaginal mesh products in his practice now. Dr. Bedestani is not qualified to give the opinions that he offers in this case and should be excluded entirely.

Alternatively, the Court should at least preclude him from opining about warnings and design issues, as he does not have specialized knowledge on either of those topics. In addition,

the Court should exclude Dr. Bedestani's unsupported *ipse dixit* opinion that the Prosima mesh was the "state of the art" during its brief time on the market.

Dated: October 18, 2018

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that the foregoing was filed on October 18, 2018, using the Court's CM/ECF electronic filing system, thereby serving notice of the filing upon counsel for all parties to the case.

/s/ Jeffrey M. Kuntz
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